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|--|---------------|----------------------|---------------------|------------------|
| APPLICATION NO.  | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/650,559   | 08/28/2003    | Jeffrey A. Engler    | U2002-0057US01      | 1600             |
| 23378  | 7590          | 02/18/2010           | EXAMINER            |                  |
| BRADLEY ARANT BOULT CUMMINGS LLP<br>INTELLECTUAL PROPERTY DEPARTMENT<br>1819 FIFTH AVENUE NORTH<br>BIRMINGHAM, AL 35203-2104 |               |                      | GANGLE, BRIAN J     |                  |
| ART UNIT   | PAPER NUMBER  |                      |                     | 1645             |
| MAIL DATE  | DELIVERY MODE |                      |                     |                  |
| 02/18/2010   | PAPER         |                      |                     |                  |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |
|------------------------------|--------------------------------------|--------------------------------------|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/650,559 | <b>Applicant(s)</b><br>ENGLER ET AL. |
|                              | <b>Examiner</b><br>Brian J. Gangle   | <b>Art Unit</b><br>1645              |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 22 October 2009.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 49-68 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) 56-63 is/are allowed.

6) Claim(s) 49-53,55 and 64-66 is/are rejected.

7) Claim(s) 54,67 and 68 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/06)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicant's amendment, filed on 10/22/2009 is acknowledged. Claims 49-50 and 54 are amended. New claims 56-68 are added. Claims 49-68 are pending and are currently under examination.

#### ***Objections Withdrawn***

The objection to the application for failing to comply with the requirements of 37 C.F.R. 1.821-1.825 because it contains amino acid sequences that are not identified, is withdrawn in light of applicant's amendment to Figure 3.

#### ***Objections Maintained***

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code on page 8. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

It is noted that the cited occurrence of improper use is only exemplary and applicant should review the specification to correct any other use of embedded hyperlink and/or other form of browser-executable code.

Applicant has amended the specification; however, the hyperlink is still present.

#### ***New Claim Objections***

Claims 54, 67, and 68 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Claim Rejections Withdrawn***

The rejection of claims 49-52 and 54-55 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn in light of applicant's amendment thereto.

The rejection of claims 49-50 and 53 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, is withdrawn in light of applicant's amendment thereto.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless —

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 49-53, 55, and 64-66 are rejected under 35 U.S.C. 102(a) as being anticipated by Telford *et al.* (WO02/34771, May, 2002; IDS filed 2/6/2004) for the reasons set forth in the rejection of claims 49-52 in the previous office action.

**Applicant argues:**

- 1. That the claims require a polypeptide with bacteriolytic and/or glycosidase activity.

Applicant argues that Telford does not disclose either activity and thus does not anticipate the claims.

- 2. That claims 62-66 are drawn to a polypeptide comprising SEQ ID NO:2 or a fragment thereof. Applicant argues that Telford does not disclose a fragment of SEQ ID NO:2.

Applicant's arguments have been fully considered and deemed non-persuasive.

Regarding argument 1, once a reference teaching a product appearing to be substantially identical is made the basis of a rejection, and the examiner presents evidence or reasoning tending to show inherency, the burden shifts to the applicant to show an unobvious difference. "[T]he PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his [or her] claimed product. Whether the rejection is based on 'inherency' under 35 U.S.C. 102, on '*prima facie* obviousness' under 35 U.S.C. 103, jointly or alternatively, the burden of proof is the same...[footnote omitted]." The burden of proof is similar to that required with respect to product-by-process claims. *In re Fitzgerald*, 619 F.2d 67, 70, 205 USPQ 594, 596 (CCPA 1980) (quoting *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977)). In the instant case, the polypeptide disclosed by Telford is 92.7%

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identical to the instantly claimed SEQ ID NO:2. Applicant has specifically claimed variants that have as little as 60% identity with SEQ ID NO:2, suggesting that a great deal of variation is possible while still maintaining the claimed activity. Furthermore, as can be seen in Garcia *et al.* (PNAS, 85:914-918, 1988; IDS filed 2/6/2004), there are streptococcal enzymes with only 53% identity to SEQ ID NO:2 that have bacteriolytic activity. Due to the structural similarity, one of skill in the art would fully expect the polypeptide disclosed by Telford to have similar activity to that of the claimed polypeptide.

Regarding argument 2, Telford specifically discloses fragments of SEQ ID NO:1388, which would necessarily encompass fragments that match fragments of the instantly claimed SEQ ID NO:2.

The instant claims are drawn to purified polypeptides with the amino acid sequence of SEQ ID NO:2 or variants of SEQ ID NO:2.

Telford *et al.* disclose a purified protein (as well as fragments of said protein which are at least 7 amino acids long) with the sequence of SEQ ID NO:1388 (see page 2, lines 1-5 and 25-30, and page 140 of the sequence listing). SEQ ID NO:1388 is 92.7% identical to the instantly claimed SEQ ID NO:2. With regard to claims 50 and 65, the polypeptides disclosed by Telford *et al.* are longer than 6 amino acids and, due to the sequence similarity, one would expect them to react with an antibody that binds to SEQ ID NO:2. With regard to claim 53 and 66, the polypeptide disclosed by Telford *et al.* contains amino acids 1-107. There is nothing in the claims requiring that the amino acids 1-107 (or 6-107, etc.) be amino acids 1-107 of SEQ ID NO:2.

### ***Conclusion***

Claims 56-63 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Gangle whose telephone number is (571)272-1181. The examiner can normally be reached on M-F 7-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on 571-272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian J Gangle/  
Examiner, Art Unit 1645

/Robert B Mondesi/  
Supervisory Patent Examiner,  
Art Unit 1645